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08/973,576	04/02/1998	BERNARD Malfroy-Camine	15390-00013U	7067

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EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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38

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

GROUP 2800
1600

Paper No. 38

Application Number: 08/973,576
Filing Date: April 02, 1998
Appellant(s): MALFROY-CAMINE, BERNARD

Eugenia Garrett-Wackowski
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/6/2003. A statement identifying the real party in interest is contained in the brief.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

Appellant's brief includes a statement that specified claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5665328

HORAN et al.

9-1997

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims.

A) Claims 14-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,4-12,24,29-33 of copending application Serial No. 08/483944. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons. While the two sets of claims differ in scope, both sets of claims encompass methods which make the same products and compositions which contain the same ingredients. Therefore, the two sets of claims under consideration in this rejection would have been prima facie obvious in view of each other to one of ordinary skill in the art at the time the invention was made for the aforementioned reasons.

B) Claims 1-5,7-10,12-22,24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method or product using the lipid glycyldioctadecylamide, does not reasonably provide enablement for the claimed inventions. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

According to applicants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, then BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Appellant indicated that there were numerous examples in the specification. However, all of the examples disclosed in the specification use a single type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while appellant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize

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in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

(11) Response to Argument

A) Claims 14-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,4-12,24,29-33 of copending application Serial No. 08/483944.

Appellant has indicated that upon indication of allowable subject that applicant will file a Terminal Disclaimer or cancel the conflicting claims in 08/483944

B) Claims 1-5,7-10,12-22,24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method or product using the lipid glycyldioctadecylamide, does not reasonably provide enablement for the claimed inventions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Regarding appellants comments, the MPEP section 2164.03 (Rev. 1, Feb. 2003) states:

However, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate

basis to support generic claims. In re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

Appellant has already previously argued that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The instant specification only provides examples using a single type of lipid of a single size. According to appellants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, then BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Appellant indicated that there were numerous examples in the specification. However, all of the examples disclosed in the specification use a single

type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while appellant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

Regarding the Malfroy-Camine declaration, paragraphs 7 and 8, according to appellants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. Thus, appellant has already indicated that the Horan et al. reference is germane to the instant invention and the issue of whether length of the hydrocarbon chain can effect intracellular versus cell membrane localization.

Furthermore, Horan et al. teach:

"In other applications, monoclonal antibodies, lectins, agonist or antagonists to tissue receptors, glycosaminoglycans, sialic acids or other molecules may be placed on the exterior surface of the cell to alter the migration patterns of the cell." (see column 5, second paragraph).

Thus, Horan et al. disclose that their teachings are relevant to a variety of different molecules, including antibodies. Regarding paragraphs 9 and 10 of the Malfroy-Camine declaration, appellant has already previously argued that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The instant specification only provides examples using a single type of lipid of a single size. According to appellants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane. The prior art rejection has been dropped based on this interpretation of the Horan et al. reference. During the interview, then BPS Schwartz inquired that in lieu of this unpredictability, how many examples of lipidized proteins were disclosed in the specification. Appellant indicated that there were numerous examples in the specification. However, all of the examples disclosed in the specification use a single type of lipid to create lipidized proteins (eg. glycyldioctadecylamide). Thus, while

appellant has argued that Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins. The claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons. The claims also state that the lipidized protein localizes intracellularly. Therefore, the enablement provided in the specification is not commensurate with the scope of the claimed inventions because Horan et al. disclose that it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane, there is only disclosure in the specification of use of a single size of lipid in the creation of lipidized proteins and the claims encompass lipidized proteins containing a lipid with a hydrocarbon tail of greater than 12 carbons.

Assuming arguendo that the Board finds the aforementioned arguments unpersuasive, then the Board should consider reinstating the previously pending prior art rejection because the only reason that said rejection was withdrawn was because

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according to appellants comments in the interviews of February 17 and 22, 2000, based on the Horan et al. reference it is unpredictable whether lipidized proteins that contain an added hydrocarbon tail of greater than 12 carbons will localize intracellularly or localize in the cell membrane.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,




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December 15, 2003

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